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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,975	01/18/2002	Limin Li	FUNC-0020-UT1	5176

22506 7590 01/09/2009

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
01/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/053,975	LI ET AL.	
	Examiner	Art Unit	
	BRANDON J. FETTEROLF	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-16,22-25,31,32 and 37-50* is/are pending in the application.

4a) Of the above claim(s) *7-16,22-25,31,32,37-42,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-6, 43 and 46-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/2008 has been entered.

Claims 1, 4-16, 22-25, 31-32 and 37-50 are pending.

Claims 7-16, 22-25, 31-32, 37-42 and 44-45 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 1, 4-6, 43 and 46-50 are currently under consideration.

The rejection of Claims 1, 4-6, 43 and 46-50 under 35 U.S.C. 102(b) as being anticipated by Brie et al. (US 5,892,016, 1999, *of record*) is withdrawn in view of Applicants arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 43, 46 and 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (IDS, US 5,891,668, 1999).

Li. et al. teach antibodies which have been raised to normal or mutated forms of TSG101 (column 8, line 59-63). Specifically, the patent teaches antibodies that specifically recognize an epitope within the coiled domain, leucine zipper and proline rich domains of TSG101 (column 8, lines 64 to column 9, line 4). In particular, the patent teaches (column 3, line 45) that the proline rich domain encompasses amino acids 130-205 of human TSG101, e.g., amino acids 140-215 of the claimed SEQ ID NO: 1. Moreover, the patent teaches that the antibodies include, but are not

limited to, polyclonal antibodies and monoclonal antibodies (column 9, lines 5-21). With regards to TSG101, Li et al. provide both the mouse TSG101 and the human homolog (column 3, lines 26-38, see below, human homolog).

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Patent No. 5891668
APPLICANT:  LI, Limin
APPLICANT:  COHEN, Stanley N
US-08-670-274B-4

  Query Match             97.8%;  Score 2002;  DB 2;  Length 380;
  Best Local Similarity   100.0%;  Pred. No. 3e-155;
  Matches  380;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          11 MVSKYKYRDLTVRETVNVITLYKDLKPVLDSYVFNDGSSRELMNLTGTIPVPYRGNTYNI 70
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db           1 MVSKYKYRDLTVRETVNVITLYKDLKPVLDSYVFNDGSSRELMNLTGTIPVPYRGNTYNI 60

Qy          71 PICLWLLDTYPYNPPICFVKPTSSMTIKTGKHVDANGKIYLPYLHEWKHPQSDLLGLIQV 130
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          61 PICLWLLDTYPYNPPICFVKPTSSMTIKTGKHVDANGKIYLPYLHEWKHPQSDLLGLIQV 120

Qy         131 MIVVFGDEPPVFSRPISASYPPYQATGPPNTSYMPGMPGGISPYPSGYPPNPSGYPGCPY 190
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         121 MIVVFGDEPPVFSRPISASYPPYQATGPPNTSYMPGMPGGISPYPSGYPPNPSGYPGCPY 180

Qy         191 PPGGPYPATTSSQYPSQPPVTTVGPSRDGTISEDTIRASLISAVSDKLRWRMKEEMDRAQ 250
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         181 PPGGPYPATTSSQYPSQPPVTTVGPSRDGTISEDTIRASLISAVSDKLRWRMKEEMDRAQ 240

Qy         251 AELNALKRTEEDLKKGHQKLEEMVTRLDQEVAEVDKNIELLKKKDEELSSALEKMENQSE 310
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         241 AELNALKRTEEDLKKGHQKLEEMVTRLDQEVAEVDKNIELLKKKDEELSSALEKMENQSE 300

Qy         311 NNDIDEVIIPTAPLYKQILNLYAEENAIEDTIFYLGEALRRGVIDLDVFLKHVRLLSRKQ 370
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         301 NNDIDEVIIPTAPLYKQILNLYAEENAIEDTIFYLGEALRRGVIDLDVFLKHVRLLSRKQ 360

Qy         371 FQLRALMQKARKTAGLSDLY 390
               ||||||||||||||||||||
Db         361 FQLRALMQKARKTAGLSDLY 380
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Note in order to expedite prosecution, the Examiner would like to address applicants arguments pertaining to the previous rejection, as they relate to the instant rejection. In response to the previous rejection, Applicants assert that the cited references do not teach all of the claimed features of the present invention. In particular, Applicants assert that Li does not teach or suggest antibodies that specifically bind to a ubiquitination-regulating domain of TSG101 protein, wherein the antibodies specifically bind to an epitope in the ubiquitination-regulating domain of TSG101 protein found in amino acid residues 1-250 of SEQ ID NO:1. Thus, Applicants assert that since Li does not teach the express feature and limitation of requiring antibodies of the present invention to specifically bind to teh ubiquitination-regulating domain of TSG101, such reference cannot

anticipate the present invention as claimed, therefore, they may not be used as a proper reference under 102 (b)

These arguments have been carefully considered but are not found persuasive.

In the instant case, the Examiner acknowledges and does not dispute Applicants assertions that Li is silent on the "ubiquitination-regulating domain of TSG101 protein". However, the Examiner recognizes that Li clearly teach antibodies, monoclonal or polyclonal, which specifically recognize the proline rich domain of human TSG101. In particular, the Li teaches that the proline rich domain of human TSG101 encompasses amino acids 130-205 of human TSG101, e.g., amino acids 140-215 of the claimed SEQ ID NO: 1. As such, an epitope within the proline rich domain appears to lie within the ubiquitination-regulating domain of TSG101 as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-5 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (IDS, US 5,891,668, 1999) as applied to claims 1, 6, 43, 46 and 49-50 above, and further in view of Ferrer et al. (Oncogene 1999; 18: 2253-2259, IDS).

Li. et al. teach antibodies which have been raised to normal or mutated forms of TSG101 (column 8, line 59-63). Specifically, the patent teaches antibodies that specifically recognize an epitope within the coiled domain, leucine zipper and proline rich domains of TSG101 (column 8, lines 64 to column 9, line 4). In particular, the patent teaches (column 3, line 45) that the proline rich domain encompasses amino acids 130-205 of human TSG101, e.g., amino acids 140-215 of the claimed SEQ ID NO: 1. Moreover, the patent teaches that the antibodies include, but are not limited to, polyclonal antibodies and monoclonal antibodies (column 9, lines 5-21). With regards to

TSG101, Li et al. provide both the mouse TSG101 and the human homolog (column 3, lines 26-38, see below, human homolog).

Li et al. do not specifically teach monoclonal antibodies raised against amino acids 1-130 of human TSG101, e.g., amino acids 10-140 of SEQ ID NO: 1.

Ferrer et al. teach that normal human TSG101 contains the ubiquitin regulatory homology domains near the N-terminus, e.g., amino acids 1-134 of human TSG101, and a canonical leucine zipper with seven leucin residues more proximal to the carboxy terminus, wherein the regions URH1 (ubiquitin regulatory-protein homology 1) and URH2a are the most conserved and specific for the E2 ubiquitin inhibitors, while the complete region (URH2 and 3) are homologous with the E2 family of proteins as a group and absent in a mutated form of TSG101 found expressed in a variety of cancers (page 2255, 1st column, 2nd full paragraph and Figure 4).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the reference so as generate monoclonal antibodies as taught by Li et al. to amino acids 1-134 of human TSG101 in view of the teachings of Ferrer et al. One would have been motivated to do so because as taught by Ferrer et al. those of the skill in the art recognize that the regions URH1 (ubiquitin regulatory-protein homology 1) and URH2a are the most conserved and specific for the E2 ubiquitin inhibitors, while the complete region (URH2 and 3) are homologous with teh E2 family of proteins as a group. Moreover, the Board of Patent Appeals and interferences has taken the position that once an antigen has been isolated, the manufacture of monoclonal antibodies against it is *prima facie* obvious. See Ex parte Erlich, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. APp. & Int. 1990).

Therefore, No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf
Examiner
Art Unit 1642

/Brandon J Fetterolf/
Examiner, Art Unit 1642